DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 12, 2014

MicroPort Orthopedics, Inc.
Mr. Byron Ledbetter
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K141235
Trade/Device Name: PROFEMUR® Renaissance® Classic Long Neck Hip Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, LPH, MBL, JDI
Dated: August 12, 2014
Received: August 13, 2014

Dear Mr. Ledbetter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141235

Device Name

PROFEMUR® Renaissance® Classic Long Neck Hip Stems

Indications for Use *(Describe)*

The PROFEMUR® Renaissance® Classic Long Neck Hip Stems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

The PROFEMUR® Renaissance® Classic Long Neck Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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MicroPort Orthopedics Inc.

510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the PROFEMUR® Renaissance® Classic Long Neck Hip Stems.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd Arlington, TN 38002 Phone: (866) 872-0211 Fax: (855) 446-2247
Date:	September 3, 2014
Contact Person:	Byron Ledbetter *Regulatory Affairs Specialist II*
Proprietary Name of Modified Device:	PROFEMUR® Renaissance® Classic Long Neck Hip Stems
Common Name:	Femoral Hip Stem
Classification Name and Reference:	888.3353 LZO Hip joint metal/ceramic/polymer semi constrained cemented or nonporous, uncemented prosthesis Class II 888.3350 JDI Hip joint metal/polymer semi-constrained cemented prosthesis Class II 888.3358 LPH Hip joint metal/polymer/metal semi-Constrained porous-coated uncemented prosthesis Class II

MicroPort Orthopedics Inc.

888.3358 MBL
Hip joint metal/polymer/metal semi-Constrained poruous-coated uncemented prosthesis
Class II

Subject Product Code and Panel Code: Orthopedics/87/LZO/JDI/LPH/MBL

Predicate Devices: PROFEMUR® Renaissance® Classic Hip Stem, K130984

Device Description

The purpose of this submission is to provide a long neck option to the predicate PROFEMUR® Renaissance® Classic Hip Stems (K130984) by adding a line extension. The PROFEMUR® Renaissance® Classic Long Neck Hip Stems are monolithic stems manufactured from a forged titanium alloy (ASTM F620) and designed for use in uncemented total hip arthroplasty. The PROFEMUR® Renaissance® Classic Long Neck Hip Stems are available in 32 configurations and are coated with titanium plasma spray conforming to ASTM F1580. The 32 configurations consist of standard and reduced flare components (14 sizes reduced and 18 sizes standard). The reduced and standard flares refer to the amount of material in the proximal-medial region. Each flare configuration is available in two neck offset options, Straight (standard) and Varus 8° (extended). The geometry, distal-from-resection, is identical to those available with the predicate device.

Intended Use

The PROFEMUR® Renaissance® Classic Long Neck Hip Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® Renaissance® Classic Long Neck Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.

MicroPort Orthopedics Inc.

Technological Characteristics of the Device
The indications for use of the PROFEMUR® Renaissance® Classic Long Neck Hip Stems are identical to those for the predicate device (K130984). The subject devices are made from an identical titanium alloy (ASTM F620) and possess an identical titanium plasma spray coating (ASTM 1580) as the predicate device. The PROFEMUR® Renaissance® Classic Long Neck Hip Stems are designed to provide geometry, distal-from-resection, which is identical to those available with the predicate device with the exception of neck length.

Nonclinical Testing
The PROFEMUR® Renaissance® Classic Long Neck Hip Stems were evaluated by proximal and distal fatigue tests in accordance with ISO 7206-4 and 6 and satisfied the acceptance criteria of each. Additionally, the PROFEMUR® Renaissance® Classic Long Neck Hip Stems were evaluated for range of motion and were deemed acceptable per ISO 21535.

Clinical Testing
Clinical data was not provided for the subject devices.

Conclusions
The indications for use and fundamental scientific technology of the PROFEMUR® Renaissance® Classic Long Neck Hip Stems are identical to those of the predicate device. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The safety and effectiveness of the PROFEMUR® Renaissance® Classic Long Neck Hip Stems is adequately supported by the substantial equivalence information, materials information, and nonclinical testing data provided within this premarket notification.